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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,447	09/08/2003	Timothy Crowley	9138-0098US	4731
28529	7590	12/28/2005	EXAMINER	
GALLAGHER & KENNEDY, P. A. 2575 E. CAMELBACK RD. #1100 PHOENIX, AZ 85016			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER

1723

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,447

Applicant(s)

CROWLEY ET AL.

Examiner

Krishnan S. Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-110 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 13-64 and 69-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12, 65-68 and 72-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1 and 3-110 are pending after the amendment of 11/4/05, of which claims 1-6, 13-64, 69-71 are withdrawn from consideration.

Election/Restrictions

Claims 70 and 71 are withdrawn from consideration as they depend from a non-elected claim 69, and recite a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7- 12, and 73-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: at indent c, the claim recites 'a filter element communicating between the first passage', which is structurally incomplete (or impossible), and omits an essential element. The filter element should be communicating "between the first passage' and 'a path of liquid filtrate flow operative to move liquid filtrate flow therealong'.

Claim Objections

Claim 81 is objected to because of the following informalities: 'nanometer' in the second last line of the claim seems to be a typo. Volume flow cannot be in nanometers. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 7-10, 65-68, 72-83, 85, 87-92, 97-105 and 107-110 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundberg et al (US 6,090,251).

Sundberg teaches a microfluidic instrument in figure 7 comprising an input (70), a first passage (76), a tangential filter in the first passage (the first of the filter 90, which is a weir type filter – see figure 8), and multiple liquid flow paths (78) downstream of the filter as claimed – for claim 7, the second and third flow paths (78) are downstream and is tangentially past the first filter (90). For claim 81, all channels 78 are downstream, because claim 81 does not recite "tangential" structure. Figure 7 shows only three channels 78, but the abstract and column 4 lines 3-10 teaches that any number of channels 78 are possible (such as five or more). All flow paths are parallel, lead to an

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output (82,84), have analytical provisions (column 1 lines 10-15, column 5 lines 15-28), and have capillary action (abstract). Tangential flow as in claim 85 over filter 90.

Claims 65-68, 98 recite the means plus function language for continuous flow, which is capillary action as disclosed in the specification (35 USC 112, sixth paragraph, means plus function language would be the corresponding disclosure or equivalents thereof). Sundberg teaches the structure recited in the claims as above.

Claim 87, 104: smooth surface, semiconductor – see materials in column 6 lines 57-67.

Claim 88, 101: several instruments, part of a device – see abstracts: microfluidic substrates; column 1 lines 5-10 describe the invention as structure for introduction of fluids into devices.

Claim 92: covering plate – see figures 7 and 8: plan and cross-sectional elevation, showing covered structures.

Claim 97: weir type opening – see figure 8.

Claim 72-80, 82,83, 89,90, 99,100, 107-110: the recitations in these claims, 'the complex fluid', blood, cell lysis, the flow times, filtrate quantities, and other 'instrument requirements' are intended use, which are not patentable. The instrument taught by the reference is capable of all these. See also column 9 lines 50-67.

Claim 102, 105: multiple receiving means – see 70, figure 7.

2. Claims 98-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Quake et al (US 2004/0248167).

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Quake teaches an instrument comprising an input (24, see figures 1 and 2), liquid receiving means 48, means for flow communication and maintenance by capillary action – channels 32. Please note that the means plus function language revokes 35 USC 112, sixth paragraph, which requires the means to be what is disclosed by the applicant, or equivalent thereof. Applicant's disclosure for the instant claims is believed to be the structure of figures 1 and 2. The Quake reference teaches same or similar structure in figure 1 and 2, but without the tangential flow weir filter. However the filter is not claimed. The instrument of Quake has more than one capillary 'further means for capillary action' as seen in figure 1 (such as channels 40,42); and other instruments (50) on the same surface. Residence time and flow volumes are intended use or functional language which are not patentable. Dimensions of claim 106 are in paragraph 153 and 187 of the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11,12, 84,86,93-96 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundberg as applied to claims 10 and 81 above, and further in view of Quake et al (US 2004/0248167).

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The teaching of Sundberg differs from claims 11 and 12 in the recitation of the details of the electro-optical means. Quake teaches a laser-optic detection system (figures, abstract, col 7 lines 50-59). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the teaching of Sundberg as one of the various intended uses of the Sundberg system for sample separation and analysis.

Claims 84,86,93-96 and 106 differ from the teaching of Sundberg in the recitation of certain dimensions of the channels. However, Sundberg teaches how to size the channels and optimize the instrument in column 9 line 50-column 10 line 38. Moreover, In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Also, Sundberg teaches channel widths, etc., in column 6 lines 9-25 with respect to the generation of capillary action. Sundberg does not teach the length of the channels. Quake teaches the length of the channels as about 1 μm to 2 cm, depending on the need for the analytical methods (see paragraph 187). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the teaching of Sundberg for analysis of the samples of Sundberg as taught by Quake.

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4. Claims 81-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brody (US 5,922,210) in view of Quake et al (US 2004/0248167).

Brody teaches an instrument comprising an input (1-figures), filter (5), passages from input to filter (4) and filter to output (6) all of which are capillary flow paths (inherent), and liquids flow by capillary action (inherent). Material is silicon wafers (example). Channel dimensions, separated particle sizes and fluid volumes – see column 3 lines 50-67, column 5 lines 4-25 and col 6 lines 13-25. the fluid to be treated, such as blood, and residence times (15 seconds), are intended use.

Instant claims add the further limitation of plurality of fluid flow paths connected to the first passage to receive flow therefrom by capillary action and channel dimensions, which Brody does not teach. Quake teaches plurality of capillary flow paths (32) from a reservoir (48) see - figure 1. which lead to an analyzer (50), and electro-optical means for testing (abstract); and channel dimensions such as length, width, etc in paragraph 153 and 187. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the teaching of Brody for the analysis of the filtered samples as taught by Brody for analysis such as DNA detection, etc as taught by Quake. One of ordinary skill in the art would also use the teaching of Brody to pre-filter the samples of Quake as taught by Brody for removing unwanted particulates.

5. Claims 107-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake as applied to claim 98 above, and further in view of Sundberg.

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Instant claims differ from the teaching of Quake in the recitation of the filter. Sundberg teaches such a filter (see figures). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Sundberg in the teaching of Quake for selective filtering as taught by Sundberg (column 9 line 50 – column 10 line 38) for subsequent analysis as taught by Quake.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

In response to the arguments re the restriction, paragraph 1, page 2 of the last office action only means that, to overcome the species restriction, applicant need to declare that the species are obvious equivalents. The argument re paragraph 2 of the last office action is not relevant, since no claims are allowed yet. Species claims would be allowable when corresponding generic claims become allowable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S. Menon
Patent Examiner
12/20/05


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